REMARKS

Claims 1-30 are pending in the present application.

Claims 1-14, 18, and 20-22 stand withdrawn from consideration. However, Claims 4 and 14 have been amended to include the term "liquid" preceding the terms "aerosol formulation" to provide consistency with the other pending claims.

Claim 17 has been canceled without prejudice or disclaimer.

Claims 15, 16, 19, 23, and 25 - 30 have been amended. Support for claim amendments are found throughout the specification and in the claims as originally filed. Claims 15 and 26 have been amended to define the "flow passage," as "capillary-sized flow passage," as recited in dependent Claim 23 and Claim 27. Furthermore, Claim 19 has been amended to change dependency to Claim 15 instead of Claim 17. No new matter has been added. Reconsideration and allowance are respectfully requested in view of the following remarks.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 17, 19, and 26-30 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Claim 17 has been canceled, making the rejection moot. Claim 19 has been amended to depend on Claim 15, which should obviate the basis for the rejection since the buprenorphine particles recited in the parent Claim 15 is further limited in Claim 19. In view of the present claim amendments, Applicants respectfully request the withdrawal of the rejection of Claims 17 and 19.

Claim 26 had been rejected for vagueness for reciting the terms "derivatives thereof." Applicants traverse and assert that a *prima facie* case of indefiniteness

has not been established. **MPEP Sec. 2171** provides that the test of indefiniteness is: "whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art ..." and the determination should be "whether or not the claims are precise, clear, correct, and unambiguous." Furthermore, "it is incumbent upon the examiner to factually establish that one having skill in the art would not have been able to ascertain the scope of protection defined by the claims when read, not in a vacuum, but in light of the supporting specification." "The Examiner bears the initial burden of establishing a *prima facie* case of failing to comply with the second paragraph of the statute." (emphasis added, quoting directly from an opinion on a decision on appeal before the Board of Patent Appeals and Interferences reversing examiner decision, *Ex part Robert D Dilliard, Sanji Hagishita and Mitsuaki Ohtani*, Appeal No. 1997-2184).

Claim 26, as amended, is directed to an aerosol generator, as amended, comprising (emphasis added):

> a liquid supply providing a liquid aerosol formulation comprising at least one thermally stable active ingredient selected from the group consisting of buprenorphine, pharmaceutically acceptable salts and esters thereof and derivatives thereof;
>
> a capillary-sized flow passage in fluid communication with the liquid aerosol formulation from the liquid supply; and
>
> a heater operable to heat the liquid aerosol formulation in at least a portion of the capillary-sized flow passage sufficiently to vaporize the liquid aerosol formulation and generate an aerosol containing the active ingredient.

Applicants assert that the appropriate standard for determining indefiniteness is an objective standard (i.e., a hypothetical person of ordinary skill in the art), and is not supposed to be subjectively based on the Examiner's opinion. Applicants submit that the terms "derivatives thereof" are within the scope of standard terminology routinely utilized, in the pharmaceutical art, for describing possible variants of

pharmaceutical compounds that could be derived from a parent compound. According to the MPEP and what is generally applicable under US patent practice, Applicants are entitled to claim chemical structural variants that demonstrate similar properties, activities, and/or functionalities of a patentably distinguishable parent compound recited as a claim element, such as buprenorphine as recited in Claim 26. Furthermore, Applicants point out that the relevant "hypothetical person" in the present technology disclosure is a person who possesses sufficient education/training in the chemical/pharmaceutical arts. Applicants submit that such persons would not find the phrase "derivatives thereof" to be indefinite in the context of Claim 26, regardless of whether or not the terms "derivatives thereof" are defined in the specification of the present application. Because a *prima facie* case of indefiniteness has not been established, Applicants respectfully request the withdrawal of the rejection of Claim 26 under 35 U.S.C. § 112, second paragraph.

Double Patenting Rejection

Claims 15-17, 19, and 23-30 stand rejected under nonstatutory obviousness-type double patenting over Claims 16-18 and 24-32 of copending Application No. 10/958,329 (U.S. Patent Publication No. 2005/0079137) for reasons stated at page 8-9 of the Official Action.

Applicants will address the non-statutory obviousness-type double patenting rejection upon indication of allowable subject matter.

Claim Rejections Under 35 U.S.C. § 102

Claims 15-17, 19, 23-24, and 26-30 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by *Rabinowitz et al.* ("*Rabinowitz*") (U.S. Patent Publication No. 2004/0202617).

MPEP §2131 provides that a claim is deemed anticipated "**only if each and every element** as set forth in the claim is found, either expressly or inherently described, in **a single prior art reference**" (emphasis added; MPEP quoting *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 2USPQ2d 1051, 1053 (Fed. Cir. 1987)). Thus, a proper *prima facie case of anticipation* requires that a single reference, provided by an Examiner, discloses each of the claimed elements as interpreted by one of ordinary skill in the art.

With respect to the rejection of independent Claim 26 (an aerosol generator, also referred herein as "the aerosol generating device") and dependent Claims 27-30, Applicants traverse and assert that a *prima facie* case of anticipation has not been established. The Official Action (at page 4) states:

> "[o]ne device used to make and deliver the said opioid containing aerosol has a proximal end, a distal end, a heating module, a power source and a mouthpiece. An opioid composition is deposited on a surface of heating module. Upon activation of a user activated switch power source initiates heating of heating module through ignition of combustible fuel or passage of current through resistive heating element. The opioid composition volatizes due to the heating of heating module and condenses to form a condensation aerosol prior to reaching the mouthpiece at the proximal end of the device."

Applicants assert that *Rabinowitz* does not disclose the aerosol generating device of Claim 26 in that *Rabinowitz* does not disclose the combination of features recited in **Claim 26**, as amended, comprising (emphasis added):

a liquid supply providing a liquid aerosol formulation comprising at least one thermally stable active ingredient selected from the group consisting of buprenorphine, pharmaceutically acceptable salts and esters thereof and derivatives thereof;

a capillary-sized flow passage in fluid communication with the liquid aerosol formulation from the liquid supply; and

a heater operable to heat the liquid aerosol formulation in at least a portion of the capillary-sized flow passage sufficiently to vaporize the liquid aerosol formulation and generate an aerosol containing the active ingredient.

As described in Examples 3 and 4 of the cited reference, *Rabinowitz's* device for generating aerosols containing buprenorphine does not include the recited "capillary-sized flow passage" component of the aerosol generating device of Claim 26. In both examples, a buprenorphine solution (comprising buprenorphine dissolved in dichloromethane and methyl ethyl ketone) was spread out in a thin layer on a sheet of aluminum foil. In both examples, the solvents, "dichloromethane and methyl ethyl ketone were allowed to evaporate. The aluminum foil was wrapped around a 300 watt halogen tube, which was inserted into a T-shaped glass tube" (emphasis added). *Rabinowitz* utilizes an aluminum foil, as both (1) a solid surface for initially depositing buprenorphine molecules; and (2) a heated surface for vaporizing buprenorphine molecules when heated by a heat source.

Applicants assert that *Rabinowitz*'s device comprising a glass tubing chamber that includes a tube-shaped heater over-wrapped/covered with a metal sheet does not anticipate the aerosol generating device of Claim 26. In particular, *Rabinowitz* does not disclose the combination of features recited in Claim 26, which includes: "a liquid supply providing a liquid aerosol formulation comprising at least one thermally stable active ingredient selected from the group consisting of buprenorphine, pharmaceutically acceptable salts and esters thereof and derivatives

thereof; a capillary-sized flow passage in fluid communication with the liquid aerosol formulation from the liquid supply ...." *Rabinowitz* merely discloses that a solution is "deposited" onto "a surface" of a heating module. Applicants assert that the claimed aerosol generating device is not disclosed or suggested in *Rabinowitz*.

With respect to the rejection of independent Claim 15 (directed to a method of generating an aerosol) and dependent claims (16, 17, 19, 23, and 24), Applicants traverse and assert that a *prima facie* case of anticipation has not been established.

Claim 15 recites a method of generating an aerosol comprising (emphasis added):

> supplying a liquid aerosol formulation to a capillary-sized flow passage,
> heating the liquid aerosol formulation in the capillary-sized flow passage so as to volatilize a liquid component thereof and form a vapor which exits from an outlet of the capillary-sized flow passage, and
> contacting the vapor with a gaseous medium so as to form an aerosol,
> wherein the liquid aerosol formulation includes at least one thermally stable active ingredient selected from the group consisting of buprenorphine, pharmaceutically acceptable salts and esters thereof.

In contrast to the method of Claim 15, *Rabinowitz's* method (described in Examples 3 and 4) requires: (1) applying a solution of buprenorphine dissolved in a solvent(s) (dichloromethane and methyl ethyl ketone) onto an aluminum sheet that wraps over a heat source; (2) evaporating the solvent(s) to form a thin layer of buprenorphine particles in a solid form on the outer surface of the aluminum sheet; and (3) heating the aluminum sheet to vaporize the solid particles of the buprenorphine layer that can form aerosols containing buprenorphine. Applicants assert that *Rabinowitz* does not disclose the method of generating an aerosol as recited in Claim 15 because the steps of "supplying a liquid aerosol formulation to a capillary-sized flow passage, heating the liquid aerosol formulation in the capillary-sized flow passage

so as to volatilize a liquid component thereof and form a vapor which exits from an outlet of the capillary-sized flow passage" is not disclosed or suggested in *Rabinowitz*. Absent a disclosure of all recited elements of independent Claim 15, a *prima facie* case of anticipation has not been established. Applicants respectfully request the withdrawal of the rejection of Claims 15, 16, 17, 19, 23, and 24.

Claim Rejections Under 35 U.S.C. § 103

MPEP §2143 provides that to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure." (MPEP sec. 2143 quoting *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

-I-

Claims 15, 17, 19, and 23-30 stand rejected under 35 U.S.C. §103(a) over *Hodges et al.* (U.S. Patent No. 6,682,716).

With respect to the rejection of independent Claim 26 (directed to an aerosol generator) and dependent claims (27-30), Applicants traverse and assert that a *prima facie* case of obviousness has not been established. Applicants assert that

Hodges does not disclose or suggest the combination of all elements recited in independent Claim 26, which includes "a liquid supply providing a liquid aerosol formulation comprising at least one thermally stable active ingredient selected from the group consisting of buprenorphine, pharmaceutically acceptable salts and esters thereof and derivatives thereof; a capillary-sized flow passage in fluid communication with the liquid aerosol formulation from the liquid supply; and a heater operable to heat the liquid aerosol formulation in at least a portion of the capillary-sized flow passage sufficiently to vaporize the liquid aerosol formulation and generate an aerosol containing the active ingredient."

In the Official Action, the following position is taken regarding *Hodges's:*

> "aerosolization device ... operably connected to the flow meter. A dose of the compound is deposited onto thin, stainless steel foil. In most cases, compound is deposited by making a solution of the compound with an organic solvent ... said foil functions as both a substrate for the drug to be delivered to the subject and the heating element for the vaporization of the drug" (emphasis added).

Applicants note that the stainless steel foil 64 (FIGS. 3-5 and 7) is not suggestive of the "capillary-sized flow passage" of the claimed aerosol generating device, in that the stainless steel foil 64 is shown and described only as a planar sheet of metal having a "constant cross section" to enable uniform distribution of heat (*Hodges*, column 9, last paragraph; column 10, first paragraph), in contrast to the "capillary-sized flow passage" of the claimed aerosol generating device. Absent a disclosure of all recited elements of independent Claim 26, a *prima facie* case of obviousness has not been established. Applicants respectfully request the withdrawal of the rejection of Claims 26-30.

With respect to the rejection of independent Claim 15 (directed to a method of generating an aerosol) and dependent claims (17, 19, and 23-25), Applicants traverse and assert that a *prima facie* case of obviousness has not been established. Applicants assert that *Hodges* does not disclose or suggest all elements recited in independent Claim 15, which includes the steps: "supplying a liquid aerosol formulation to a capillary-sized flow passage, heating the liquid aerosol formulation in the capillary-sized flow passage so as to volatilize a liquid component thereof and form a vapor which exits from an outlet of the capillary-sized flow passage."

Hodges's method for vaporization of a compound of interest requires: depositing and "rapidly heating a thin film of a compound" to vaporize the compound; and flowing air "across the surface of a compound to sweep away vaporized molecules ... this process drives vaporization as opposed to condensation and therefore enables aerosol formation at relatively moderate temperatures" (column 14, lines 7-12). Several preferred ranges of suitable thickness of compounds deposited as thin films are also provided (column 14, lines 29-31).

In contrast, Applicants note that the claimed method involves "supplying a liquid aerosol formulation to a capillary-sized flow passage, heating the liquid aerosol formulation in the capillary-sized flow passage so as to volatilize a liquid component thereof and form a vapor which exits from an outlet of the capillary-sized flow passage, contacting the vapor with a gaseous medium so as to form an aerosol. Absent a disclosure of all recited elements of independent Claim 15, a *prima facie* case of obviousness has not been established. Applicants respectfully request the withdrawal of the rejection of Claims 15, 17, 19, and 23-25.

-II-

Claims 15, 17, 19, and 23-30 stand rejected under 35 U.S.C. §103(a) in view of *Nguyen et al.* (U.S. Patent No. 7,040,314).

Applicants traverse. MPEP §706.02(l)(2) provides that a prior art reference can be disqualified under 35 U.S.C. §103(c), if: "the subject matter which would otherwise be prior art to the claimed invention and the claimed invention ... [are] commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made or be subject to a joint research agreement at the time the invention was made. " Applicants note that the '314 patent can be disqualified as prior art reference in that the '314 patent and the present application were subject to an assignment agreement at the time of the present invention. As such, it is respectfully submitted that *Nguyen* is not available as a prior art reference for basing an obviousness rejection under 35 U.S.C. §103(a). Applicants respectfully request the withdrawal of the rejection of Claims 15, 17, 19, and 23-30.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment, or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of present application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: March 27, 2007

By: 
Loree J. Kim
Registration No. 53126

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620